NEWS

References on news stories are in the versions on bmj.com

bmj.com
Put health at the heart of transport policies, says BMA report

BMA and Unison attack planned "pay cartel" in southwest England

Jacqui Wise LONDON

Nineteen trusts in southwest England want to break from national pay, terms, and conditions, indicates a leaked document obtained by the *Sunday Times*.

The trusts have formed the South West Pay, Terms and Conditions Consortium to examine ways to deliver savings. Health unions and professional organisations have labelled the consortium a "pay cartel" that would push through regional changes that would not have been possible on a trust by trust basis.

The leaked document suggests terminating all staff contracts and reoffering them on different terms. The new terms could include pay cuts of up to 5%, an end to overtime, and reduced holiday leave. The terms would be aimed initially at employees on Agenda for Change contracts, which cover all NHS staff apart from doctors and senior managers, but the BMA has warned that medical staff members are not outside the target group. The document states that the review "must be all-encompassing and across all staff groups."

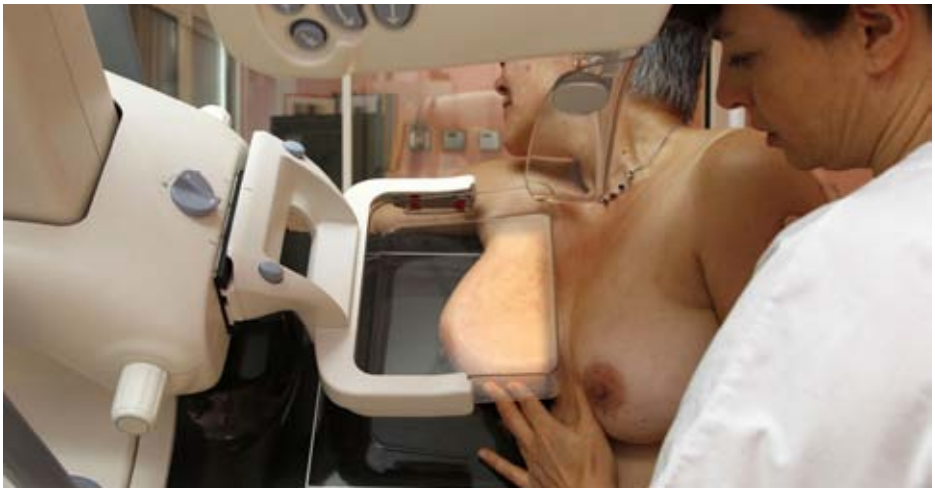
The consortium has appointed a director, and all 19 members have agreed to contribute £10 000 each to allow the procurement of professional advice and legal and human resources support.

The Royal Devon and Exeter NHS Foundation Trust, one of the members of the consortium, said in a statement, "Consortium members believe that rather than watch national negotiations on this issue from a distance, we should, as responsible employers and healthcare providers, work together within the South West region now to give all of our respective organisations the best opportunity to be sustainable in the years ahead."

A BMA spokesman said, "The focus should be on NHS staff and managers working together to find more efficient ways of working and of shaping services, while at least maintaining quality."

Christina McAnea, head of health at the public sector union Unison, condemned the plan as unfair. "Breaking national pay agreements will undo years of work creating a level playing field for pay and conditions across the NHS. Patients will pay the ultimate price, as workers who can move to areas where wages are higher will do so."

Cite this as: *BMJ* 2012;345:e4843



ASTIER-CHRU LILLE/SPL

Breast cancer mortality fell in Sweden at a similar rate before and after screening was introduced

Screening has little or no effect on breast cancer deaths, data show

Susan Mayor LONDON

Mammography screening has little or no effect on mortality from breast cancer in women aged 40-69, shows an analysis of Swedish figures published this week. But commentators argue that trends in breast cancer deaths cannot be used to evaluate screening in isolation from developments in diagnostic methods and treatment.

Regular mammography screening for women aged 40-69 years was introduced gradually in Sweden from 1974, achieving nationwide coverage across all 21 counties in 1997. Attendance for mammography screening is now among the highest recorded in any country, with 75% to 85% of eligible women attending screening regularly.

Researchers led by Philippe Autier, director of the International Prevention Research Institute in Lyon, France, hypothesised that the gradual introduction of screening into different Swedish counties would be reflected in county specific mortality over the past 20 years. They analysed data from the Swedish Board of Health and Welfare from 1960 to 2009 to assess trends in breast cancer mortality in women aged 40 and older by the county where they lived.[1]

The group expected to see a gradual reduction in breast cancer mortality after regular screening was introduced. But instead the results showed that breast cancer mortality had already started to fall in 1972, before mammography screening was introduced. Deaths then continued to fall at a similar rate to that in the pre-screening period.

Breast cancer death rates in Swedish women aged 40 years and over fell by 0.98% each year between 1997 and 2009. The rate fell continuously in 14 of the 21 Swedish counties. It declined sharply in three counties during or soon after the implementation of screening, fell sharply in two counties at least five years after screening began, and increased in two counties after screening began.

Overall, the decline in breast cancer mortality in counties that implemented screening in 1974-8 was similar in the 18 years after the programmes were introduced to the downward trend before they started.

"It seems paradoxical that the downward trends in breast cancer mortality in Sweden have evolved practically as if screening had never existed," said Autier. "Swedish breast cancer mortality statistics are consistent with studies [in Norway and Denmark] that show limited or no impact of screening on mortality from breast cancer."[2-4]

In an accompanying editorial Michael Vannier, from the University of Chicago Medical Center, argued that the limitations of treatment have a greater bearing on mortality from breast cancer than the shortcomings of screening.[5] Using mortality to evaluate the effect of screening is simplistic, he wrote.

Cite this as: *BMJ* 2012;345:e4847

NICE calls for more risk assessments for diabetes

Jacqui Wise LONDON

Risk assessments for type 2 diabetes should be offered to all adults over 40 and those aged 25-39 who are of South Asian, Chinese, African-Caribbean, or black African descent, according to new public health guidelines from the National Institute for Health and Clinical Excellence.

The first stage of this risk assessment could be carried out in GP surgeries as part of the NHS Health Check programme but equally could take place in workplaces, job centres, pharmacies, faith centres, libraries, or shops. NICE says it is not advocating a national screening programme for type 2 diabetes but wants to encourage people to identify their own personal risk and make lifestyle changes that can delay or prevent them from developing the condition.

The guidance calls for a new accreditation body to oversee effective practice in type 2 diabetes. The proposed body would be facilitated by NICE and involve professional associations, royal colleges, academic centres, and community and voluntary sector organisations.

The guidelines recommend a stepped or staged assessment of risk. The first stage involves adults assessing their own risk on paper or online using a validated risk assessment score, such as the one found on the Diabetes UK website (www.Diabetes.org.uk/Riskscore/). The risk assessment can be used alongside the NHS Health Check Programme.

Those assessed as high risk should then be offered a fasting blood glucose test or a glycated haemoglobin (HbA_{1c}) test.

The guidelines state that those identified at high risk should be offered an intensive lifestyle change programme with tailored advice and support for people to be more physically active, maintain a healthy weight, and eat a healthy diet. These programmes should involve at least eight meetings over 9-18 months with follow-up for at least two years. The guidelines also include advice on diet, exercise, and weight loss and when prescription of metformin and orlistat would be appropriate.

GPs should keep an up to date register of people's level of risk, the guidelines say.

See HEAD TO HEAD, p 18

Cite this as: *BMJ* 2012;345:e4778

MPs say health damage from alcohol misuse has been underplayed

CLIVE DIXON/REX

The alcohol industry should admit that its advertising affects attitudes, MPs say

Adrian O'Dowd LONDON

The government's focus on antisocial behaviour and public order when dealing with alcohol misuse risks overshadowing the importance of the damage to health from excessive drinking, claim MPs in a new report.

In its response to the government's alcohol strategy, the parliamentary select committee on health calls for clearer and more precise objectives in tackling alcohol misuse than are currently given by the government.[1]

The committee's report analyses the government's alcohol strategy, published in March by the Home Office, which set out plans to introduce a minimum unit price for alcohol and to work with the drinks industry to provide clearer information on alcohol units.[2]

Although the Health Committee welcomed much of the strategy, serious flaws remain, according to the committee. "We believe that the health impact of the misuse of alcohol is more insidious and pervasive" than the strategy allows.

Cite this as: *BMJ* 2012;345:e4899

GPs' prescribing of antipsychotics falls as cases of dementia rise

Zosia Kmietowicz LONDON

The proportion of dementia patients being treated in the community in England who are prescribed antipsychotic drugs fell from 17% in 2006 to 7% in 2011, shows a national audit of nearly half the country's general practices.[1]

At the same time, the number of cases of dementia is rising. The national dementia and antipsychotic prescribing audit shows that the annual number of new diagnoses of dementia in the participating practices rose by 68%, from 18 762 in 2006 to 31 455 in 2011.

The audit, which collected information on 197 000 people with dementia from more than 3800 general practices in England (46%), also found that the rate of prescribing antipsychotics in people with dementia was six times as high in some areas as in others. In London, for example, the prescribing rate was about 2% of patients, while in the north west it was about 13%.

Alongside reduced prescribing of antipsychotics, there was a similar reduction in prescription rates for antidepressants and hypnotics. However, the report cautions that it does not capture the treatment of patients with dementia in hospitals and other specialist facilities.

Tim Straughan, chief executive of the NHS's Information Centre for Health and Social Care, which conducted the audit, said, "It is encouraging that prescribing of antipsychotic drugs is falling. However, it is clear that the picture nationally is mixed and that everyone involved in the care of those with dementia needs to look carefully at how they compare with others in their practices."

2%
LONDON

Jeremy Hughes, chief executive of the Alzheimer's Society, said, "This momentous achievement is not just about statistics, it is about the lives of tens of thousands of people with dementia. Credit is due to the many doctors, nurses, and care workers without whom this would not have been possible.

"However, there are still tens of thousands more people—both diagnosed and undiagnosed—having their lives put at risk by these drugs, and some parts of the country are failing to reach the mark. Now is the time to move from fourth gear to fifth to ensure that everyone's prescriptions are reviewed and that only those people who benefit are kept on antipsychotics. They must only be a last resort."

13%
NORTH WEST

MAYAŠLEČA/WIKI COMMONS

In 2009 a report by the Department of Health said that antipsychotic drugs were causing about 1800 deaths among people with dementia every year in the UK.[2] It said that service provision had not kept pace with the growth in the number of people with dementia.

It said that about a quarter (180 000) of the 750 000 people with dementia in the UK were taking antipsychotics even though these drugs were appropriate for just 36 000.

Cite this as: *BMJ* 2012;345:e4861

PAULA SOLLOWAY/ALAMY

Adults who are assessed as high risk should be offered a blood glucose test and lifestyle advice

Activists say UK is seeing "massive" rise in campaigns against plain packets for cigarettes

Zosia Kmietowicz LONDON

The tobacco industry and its affiliates have stepped up their lobbying in the United Kingdom against proposals to introduce standardised plain packaging on cigarettes and other tobacco products, say health campaigners.

The Department of Health launched a consultation in April on whether tobacco products should be sold in standardised packaging.[1] Packaging would be a standard colour with no branding, and text would be in a standard font.

Since then there has been a "massive" rise in campaigning against plain packaging, said Andrew Rowell, a research fellow at the University of Bath.

On 6 July Japan Tobacco International (JTI) announced that it was a launching a £2m campaign "to share its views on the potential consequences of enforcing standardised cigarette packs in the UK." Advertisements sponsored by JTI appeared in the press at the weekend attacking the department's proposals for being "policy based evidence"—evidence that is "gathered to support a chosen outcome"—as opposed to "evidence based policy."

The industry claims that plain packaging will be easier to fake and that children will be targeted by smugglers. Other groups claim that plain packaging threatens free market principles.

Cite this as: *BMJ* 2012;345:e4856

Performance enhancing drugs or techniques may exist that can't yet be detected, experts admit

Nigel Hawkes LONDON

Half of all competitors—and all those who win medals—can expect to be tested for performance enhancing drugs at the London Olympics, the organisers have announced.

A 150 strong team will take more than 6000 samples from Monday 16 July to the end of the games for analysis at a laboratory that will run 24 hours a day, seven days a week.

But do performance enhancing techniques exist that cannot be detected and that may emerge only years later, when somebody admits to having used them to win a medal in London? Leading sports medicine scientists at a media briefing at the Science Media Centre in London on 16 July admitted that there may be.

Among well established methods, autologous blood transfusions can be used by athletes to boost their oxygen carrying capacity by transfusing their own blood, stored earlier, just before competition. The transfusions can be detected by measuring the ratio of mature to immature red cells in the blood, but only if athletes are tested regularly, said Chris Cooper, professor of biochemistry at Essex University. Tyler Hamilton, the US cyclist who won a gold medal in the time trial at the 2004 Athens games was subsequently accused of this form of doping, and in 2011 he returned the medal after admitting the offence.

More sophisticated techniques also exist, such as gene doping, Cooper said. An athlete might inject a gene to enhance muscle growth, blood production, endurance, oxygen dispersal, or even pain perception, and it would prove undetectable. But Steve Harridge, professor of human and applied physiology at King's College London, said that there was no concrete evidence that this was occurring, and he believed it would be unlikely for "many many years."

Although experiments in mice had shown increases in muscle mass from injections of the gene for insulin-like growth factor 1 (IGF-1), he said, it was not clear that these bigger muscles were better muscles or that creating them by gene therapy would lead to better performance in humans. The risks of doing so might be considerable.

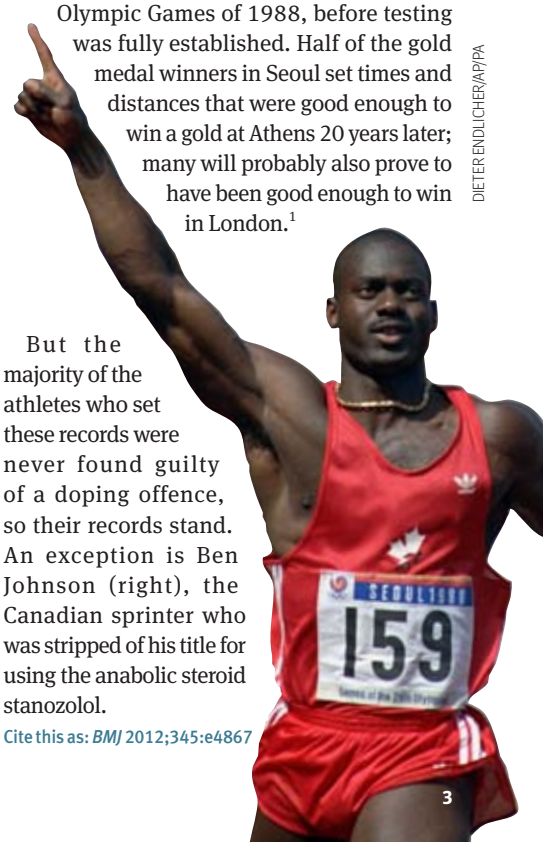
He said that trials of gene therapy to treat diseases such as cystic fibrosis had so far been disappointing, and translating the animal data to humans was not straightforward. "There are so many unknowns that I would be surprised if any athletes were starting injecting genes," he said.

The World Anti-Doping Agency agrees, though it added gene doping to its list of prohibited substances in 2003 and has been working with scientists to develop a test. This is not simple, Cooper said, and would probably require a muscle biopsy to detect evidence of the vector used to carry the gene.

"With every emerging technique, we may not know for several years that it has been used until an athlete owns up," said Andy Miah, professor of ethics and emerging technologies at the University of the West of Scotland. "If gene doping is effective, it will happen."

Traditional methods of doping are still in use, despite the testing regime, because by careful timing athletes may hope to avoid a positive test result. Last week a 4×400 m relay runner, Debbie Dunn, withdrew from the US team after a test showed high concentrations of testosterone in one sample she had given; the second sample has yet to be tested.

The difference that doping makes is shown by the extraordinary records set at the Seoul Olympic Games of 1988, before testing was fully established. Half of the gold medal winners in Seoul set times and distances that were good enough to win a gold at Athens 20 years later; many will probably also prove to have been good enough to win in London.[1]



DIETER ENDLICHER/AP/PA

But the majority of the athletes who set these records were never found guilty of a doping offence, so their records stand. An exception is Ben Johnson (right), the Canadian sprinter who was stripped of his title for using the anabolic steroid stanozolol.

Cite this as: *BMJ* 2012;345:e4867

IN BRIEF

Drugs agency consults on early access to drugs in development: The UK Medicines and Healthcare Products Regulatory Agency has launched a 12 week consultation on proposals to launch a scheme that gives patients with life threatening, chronic, or debilitating conditions early access to drugs that are still being developed, usually having completed phase III trials but sometimes just after phase II. Comments can be sent to earlyaccess@mhra.gsi.gov.uk until 5 October.

TV viewing in young children is linked to weight gain: Children who watch more than the average number of hours of television between the ages of 2 and 4 years old risk larger waistlines by age 10. The Canadian study of 1314 children found that the average child watched 8.8 hours each week at the age of 2 and 14.8 hours at age 4.[2] The effect of 18 hours of television at 4.5 years of age would by the age of 10 result in an extra 7.6 mm on the waistline, it found.

Doctors need to learn about prescribing exercise: Too few doctors understand the benefits of exercise or what it can treat, says the Royal College of Physicians.[1] To rectify the situation a national strategy for physical activity, health, and wellness should be developed as a legacy of the London 2012 Olympics and Paralympics, it says.

Trust is fined for using wrong address for patient: St George's Healthcare NHS Trust, London, has been fined £60 000 by the information commissioner after a patient's sensitive medical details were sent to the wrong address. Trust staff failed to use an updated address for the patient that was supplied before the examination or to check that the address on their local patient database matched that on the "spine," the NHS national database, which was correct.

Patients with arthritis are warned against unlicensed treatment: Patients have been warned against buying Arthroplex capsules and gel for arthritis and other medical conditions because it is unlicensed and has not been tested fully, says the UK Medicines and Healthcare Products Regulatory Agency. There have been over 70 complaints about the product's advertising, which states, "Feel your aches and pains fade in 48 hours! And then disappear forever."

Cite this as: *BMJ* 2012;345:e4824

Health "reforms" tried to square the policies of Lib Dems and Tories

Nigel Hawkes LONDON

The widely held view that the health secretary for England, Andrew Lansley, was the sole begetter of his own political misfortunes over the Health and Social Care Act is mistaken, concludes a new account of the controversial legislation.[1]

Nick Timmins, former public policy editor of the *Financial Times*, finds the fingerprints of the Liberal Democrats all over the bill and identifies the confusion that arose in the weeks after the coalition was formed as the key to understanding why an evolutionary change became revolutionary turmoil.

In *Never Again*, published by the King's Fund and the Institute for Government, Timmins traces the history of the legislation from published sources and through interviews with those involved.

He told a meeting at the institute on 12 July that among the relatively few who declined his requests for interviews were Oliver Letwin and Danny Alexander, Conservative and Liberal Democrat respectively, who in the weeks after the coalition was formed had the job of turning the sketchy coalition agreement into a programme for government. This was done in haste and with boldness, the Tories, in Timmins's opinion, having "over-absorbed" Tony Blair's complaint at the end of his premiership that he had wasted his first term by not being ambitious enough.

Letwin and Alexander had to square two conflicting views of where the NHS in England should go: the Conservatives believing in markets, the Liberal Democrats in democracy. Lansley, to his irritation, was not consulted. The outcome was a muddle—a "cut and shut" job, according to one Number 10 insider, in which

Virgin Care to take over services for children and young people in Devon

Matthew Limb LONDON

The private health company Virgin Care is about to secure a £132m contract in southwest England that will extend its reach in providing core NHS care. The company has been named preferred bidder by NHS Devon and Devon County Council to run integrated NHS and social care services for children and young people over a three year period.

A contract is expected to be awarded in the autumn after further negotiations, enabling Virgin Care to take over 1100 staff—mostly employed by NHS Devon—from 2013.

The company would run services for children with physical, sensory, and learning disabilities; health visiting and school nursing; and mental health and wellbeing services, in the area covered by Devon County Council, excluding Torbay and Plymouth. Altogether, more than 160 000 children live in this catchment area.

The contract, which is worth £44m annually and could extend to five years, does not include child protection, which will continue to be the responsibility of specialist children's social workers within Devon County Council.

NEIL MOCKFORD/FILM MAGIC

Virgin Care, owned by Richard Branson (above), will take over 1100 staff

The decision to go out to tender stemmed from the previous Labour government's commissioning policy for community services, which meant NHS Devon, as a primary care trust, could no longer provide the services directly.

NHS Devon and Devon County Council said appointing a "single, accountable organisation" to run the services on their behalf "provided the best opportunity to maintain and strengthen the integration of the services."

They said the latest announcement followed consultation with young people, parents, and carers; safeguarding, governance, and technical experts; school head teachers; and GPs and other professionals.

Rebecca Harriott, NHS Devon's director of commissioning development, said a key consideration was to keep the integrated services together and develop them.

Harriott said, "We know these are important and sensitive services and it is vital to ensure that everyone can be confident that a winning bidder is able to deliver the best possible outcomes from children and young people across Devon.

"Once a single service provider has been appointed there will be new opportunities for innovative approaches to meet the needs of children and their families."

Virgin Care defeated two rival bids from consortiums.

Cite this as: *BMJ* 2012;345:e4835


DANNY LAWSON/PA

DAVID JONES/PA

Plans for the NHS were first drawn up by Danny Alexander (left) and Oliver Letwin (right)

the good back half of a crashed car is welded to the good front half of another wreck. Others called it "half horse, half donkey" or "a spatchcocked mess." (All officials quoted were granted anonymity, so who came up with these epithets we do not know.)

Particular derision was directed at the Letwin-Alexander model for primary care trusts, which suggested that they should consist partly of directly elected individuals, to give local patients a stronger voice, with the rest appointed by local authorities and the chief executive appointed by the health secretary. "Quite how this structure was meant to work is utterly unclear," Timmins writes. "A body with at least some democratic legitimacy would be operating beneath an administrative body—the strategic health authorities—that had none, while also being answerable to the new, but entirely appointed, not elected, independent board" (the NHS Commissioning Board, as it became).

Lansley thought this "completely nuts" (not his words) but was unable to influence it. He ignored it and set about trying to find a way round it. The Liberal Democrat manifesto had promised to abolish strategic health authorities, though the pledge went unmentioned in the Letwin-Alexander plan. The Conservatives had promised to hand commissioning over to GPs. If both promises were implemented—together with the newer idea of health and wellbeing boards and the transfer of public health to local authorities—there seemed little role left for primary care trusts. There was no need for them. Lansley and his deputy, Paul Burstow, agreed that they should go.

"At one stroke we were free," an official told Timmins. The Letwin-Alexander plan was dead, and Lansley was greeted with a roar of approval in parliament when he announced the abolition of the primary care trusts.

But this escape had turned an evolutionary process of building on Labour's reforms into a structural upheaval of exactly the type that the coalition had promised would not be undertaken. The price was a bill of stupendous complexity and length.

Civil servants told Timmins that they had warned Lansley of the scale of what he now planned, at a time when the service also had to make big productivity savings. They also offered him a smaller, simpler bill. But he was adamant that he wanted to go ahead, in Timmins's opinion because mere tinkering without legislation would be too easy to reverse.

Lansley wanted to make permanent a set of reforms that had hitherto been "half baked," as he himself told Timmins. As Timmins put it, "It had to be nailed down so the next secretary of state couldn't change it by ministerial direction."

From this flowed the political problems that bogged the bill down for so long.

REVIEW: See p 38

Cite this as: *BMJ* 2012;345:e4833

Hospitals can earn 49% of their income from private patients from October

Zosia Kmietowicz LONDON

NHS hospitals in England will be able to increase the proportion of money they earn from private patients to 49% from 1 October, the Department of Health has announced.

The change to how much money foundation trusts can earn from non-NHS work was introduced in the Health and Social Care Act.[1] The original bill had said that there was nothing to stop a foundation trust from making all its money from private patients. But during its passage through the House of Lords peers voted in an amendment that said that most of a hospital's work must be NHS, meaning that 51% of their income should come from treating NHS patients.

All of England's 248 trusts are expected to become foundation trusts in the next couple of years. However, doubts have been raised that at least 20 will not meet the financial criteria to be granted foundation status,[2] and many others may need to merge or be taken over to become foundation trusts.[3]

When foundation trusts were created in 2002-3, the amount of income they could earn from non-NHS work was capped at a level set at what they made from private patients at the time. However, some specialist cancer and children's hospitals had caps of up to 30%.

In December a health department spokeswoman said that raising the cap to 49% for all foundation trusts would allow them to expand the range of services they offered.[4] "This does not represent privatisation of the NHS," she said. "Services for NHS patients will be safeguarded, because foundation hospitals will still have as their core legal purpose a duty to provide services to them. The amendment we are making provides further reassurance on this duty."

Ron Singer, a retired GP and currently president of the Medical Practitioners' Union, part of the union Unite, told the *BMJ* that allowing NHS hospitals to generate 49% of their income from private work "is the clearest evidence yet that the intention of the government is to enable private sector involvement to interfere with the running of the NHS as a public service. It is inevitable that when an NHS hospital gets into financial trouble it will try to increase its income from private patients, putting NHS patients at the back of the queue—a retrograde and regressive step."

Cite this as: *BMJ* 2012;345:e4823

About female genital cosmetic surgery

Juliet Dobson BMJ

This line drawing comes from an animated film made by the Wellcome Trust to inform women about the pros and cons of female genital cosmetic surgery. The surgery, which consists in cutting back the inner labia, is usually performed in the private sector, but last year 2000 labiaplasties were carried out in the NHS, up from 400 in 2006.

The film, entitled *Centrefold* and created by Ellie Land, aims to document what is involved in the procedure and its varying outcomes. It follows the stories of three women aged 24 to 41.

It is accompanied by a short documentary containing interviews with Sarah Creighton, a gynaecologist at University College London Hospital, and Lih-Mei Liao, a psychologist at the same hospital.

Both films will be available for the public to download free online at www.thecentrefoldproject.org on Friday 20 July 2012.

Cite this as: *BMJ* 2012;345:e4819

Combating attacks on health workers

Annabel Ferriman LONDON

This representation of a sick refugee who died because fighters shot the camp's healthcare workers and stole the camp's drugs is part of an exhibition opening on London's South Bank on Wednesday 25 July and running throughout the Olympic and Paralympic Games.

"Perspectives" has at its centre the Red Cross and the Red Crescent's campaign to stop attacks on healthcare workers and patients and features black and white pictures by Tom Stoddart along with images of people deprived of safe access to healthcare in situations of armed violence.

For more information on the exhibition see www.78perspectives.com.

Cite this as: *BMJ* 2012;345:e4862

UK favours open access to all for publicly funded research

Nigel Hawkes LONDON

The government has accepted the recommendations of the Finch report on open access to published research and aims to make all publicly funded research available to everyone.

It agrees with the view of the working group led by Janet Finch,[1] professor of sociology at Manchester University, that the "gold model" of open access, where the costs of publication are paid up front by the authors, is the right route. To pay for these changes, Research Councils UK (RCUK) has announced that in future it will make block grants available to universities and other approved organisations, rather than earmarking part of each research grant for this purpose.

However, RCUK gave no undertaking that these block grants will be new money, so they are likely to reduce the amount available for supporting research, at least in the short term. The Finch report estimated that the transition costs would be £50m to £60m a year, caused by the need to pay traditional subscriptions together with the new article processing charges during a period of undetermined length while the open access model spreads. If open access is not adopted worldwide, these "double running" costs could continue for years.

In its formal response to the Finch report, the Department of Business Innovation and Skills said that publishers who choose not to opt for article processing charges should be allowed a "short" embargo period between a paper's publication and when it becomes open access, to cover their costs through subscription income.[2] It did not specify how long that should be; Finch said that publishers might be put at risk by an embargo period of less than 12 months.

The RCUK policy is more specific, calling for an embargo of only six months. It says: "Research Councils UK will accept a delay of no more than six months between online publication and a research paper becoming open access, except in the case of research papers arising from the Arts and Humanities Research Council and the Economic and Social Research Council, where the maximum embargo is 12 months." The RCUK policy will come into effect from 1 April 2013.[3]

David Willetts, the universities and sciences minister, told the *Guardian* newspaper that the transition costs would represent only 1% of the total research budget, while the benefits of open access, he believed, would be "way beyond any £50m from the research budget."[4]

In a comment released by the Department for Business Innovation and Skills he added, "Removing paywalls that surround taxpayer-funded research will have real economic and social benefits. It will allow academics and businesses to develop and commercialise their research more easily and herald a new era of academic discovery."

Cite this as: *BMJ* 2012;345:e4878

FDA approves first drug to prevent HIV infection in high risk individuals

Bob Roehr WASHINGTON, DC

The US Food and Drug Administration this week approved for the first time a drug for use in the prevention of HIV infection. The drug, Truvada, is one of the most commonly used components of an anti-HIV "cocktail" regimen in the United States and Europe.

Truvada is two drugs combined in a single pill, tenofovir disoproxil fumarate and emtricitabine. Its preventive use is commonly referred to as PrEP (pre-exposure prophylaxis). Studies in different groups at high risk of infection have shown its efficacy.[1]

It was approved "to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners," said Debra Birnkrant in a telephone press conference with reporters. She is director of the Office of Antimicrobial Products at the FDA's Center for Drug Evaluation and Research.

Although the incidence of HIV in the US has held steady for about a decade, at about 50 000 new infections a year, it has increased in some groups, notably young men from ethnic minority groups who have sex with men, she said. "These data show that treatment and new prevention methods are needed in order to have a major impact on the HIV epidemic in this country."

She added, "Truvada for PrEP represents another effective, evidence based approach that can be added to other prevention methods to help reduce the spread of HIV . . . [when] used daily as part of a comprehensive HIV prevention strategy that includes other prevention measures."

After concerns discussed at an advisory committee meeting in May, the FDA has added a "black box warning" to the label requiring that "a negative HIV test must be documented before prescribing the drug and throughout use of PrEP."

Some people fear that PrEP might lead to "disinhibition" and hence greater risk of infection because of riskier sex and less condom use, but Birnkrant said that the placebo controlled studies did not support that fear. Furthermore, she said, there is reason to believe that adherence might increase in real world use because people know that they are being prescribed a drug whose effectiveness has been proved.

The drug has been widely used for a decade. There are some long term problems of bone and kidney toxicity that are "for the most part manageable," said Birnkrant.

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Cite this as: *BMJ* 2012;345:e4879